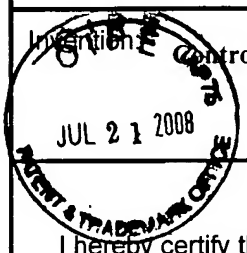
CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): **Ralph Lilly**			Docket No. **Anon-001:C**	
Application No. **10/803,259**	Filing Date **18 March 2004**	Examiner **Lena Najarian**	Customer No. **021897**	Group Art Unit **3626**

Invention: **Controlled Substance Tracking System and Method**



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is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

21 July 2008
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TRANSMITTAL LETTER
(General - Patent Pending)

Docket No.
Anon-001:C

In Re Application of: **Ralph Lilly**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/803,259	18 March 2004	Lena Najarian	021897	3626	5397

Title: **Controlled Substance Tracking System and Method**

COMMISSIONER FOR PATENTS:

Transmitted herewith is:

1) Return Postcard; 2) Check Nos. 23492+23493 **in the amount of 405.00 ($405.00 For RCE & 2 Month Extension Fees); 3) Transmittal Letter (General - Patent Pending); 4) Petition for Extension of Time (Small Entity); 5) Request for Continued Examination (RCE); 6) Copy of the Response to the Final Office Action dated 22 February 2008; 7) a copy of the Final Office Action date 22 February 2008; and 8) a copy of the Advisory Action dated 7 July 2008.**

in the above identified application.

- ☐ No additional fee is required.
- ☒ A check in the amount of **$575.00** is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **13-2166** as described below.
  - ☐ Charge the amount of
  - ☒ Credit any overpayment.
  - ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Signature

Dated: **21 July 2008**

William E. Johnson, Jr.
Reg. No. 22,719
The Matthews Firm (Customer No. 021897)
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Houston, Texas 77057
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cc:

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,259	03/18/2004	Ralph B. Lilly	Anon-001:C	5397

21897 7590 07/09/2008

THE MATTHEWS FIRM
2000 BERING DRIVE
SUITE 700
HOUSTON, TX 77057

EXAMINER	
NAJARIAN, LENA	
ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
07/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)	
10/803,259	LILLY ET AL.	
Examiner	**Art Unit**	
LENA NAJARIAN	3626	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 June 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *NONE*.
   Claim(s) objected to: *NONE*.
   Claim(s) rejected: *1-4,6-10 and 22-24*.
   Claim(s) withdrawn from consideration: *NONE*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626

Continuation of 3. NOTE: The amendment to claim 22 changes the scope of the claim and requires further search and consideration.

Continuation of 11.
Applicant's arguments filed 6/20/08 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 6/20/08.

(1) Applicant argues that the Examiner, on the one hand, has acknowledged that claims 1-4, 6-10 and 22-23 were not amended in the response to the Office Action dated September 26, 2007. On the other hand, the Examiner concludes in paragraph eleven (11) of this current Office Action that the Applicant's Amendment necessitated the new grounds of rejection presented in this Office Action.

As per the first argument, the Examiner respectfully submits that she never indicated that claim 23 was not amended. In fact, the Examiner clearly noted the status of the claims in paragraph 1 of the Office Action mailed February 22, 2008, including the statement that claims 23 and 24 were newly added in the amendment filed December 26, 2007. As such, it is clear that the addition of new claims necessitated the new grounds of rejection presented in the Office Action mailed February 22, 2008. Furthermore, the Examiner indicated in paragraph 9 that Applicant's arguments were fully considered but were not found to be persuasive and Applicant's arguments were addressed. Therefore, the Final Action is not premature and is indeed proper.

(2) Applicant argues that in light of the fact that the Examiner acknowledges that the Cunningham reference and Borsand reference do not teach or suggest the generation of one or more patterns which are indicative of prescription drug abuse, there does not seem to be any support for the concept that the previous amendment filed by the Applicant necessitated the characterization of this previous amendment as necessitating the new grounds of rejection presented in this Office Action.

As per the second argument, the Examiner never made such statements. The Examiner merely presented the reference of Edelson to address newly added claims 23 and 24. In particular, the Examiner addressed the limitation of indicating prescription duplication or multi-source prescription abuse.

(3) Applicant argues that there is no teaching in the references calling for generation of patterns indicative of drug abuse. The present invention is directed to something much greater than merely monitoring the prescription history of the patient.

As per the third argument, the Examiner respectfully submits that she gave the terms "abuse" and "patterns" the broadest reasonable interpretation in light of the Specification. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's arguments directed towards claim 22 will not be addressed since the amendment has not been entered.

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PATENT APPLICATION FEE DETERMINATION RECORD
Substitute for Form PTO-875

Application or Docket Number	Filing Date	To be Mailed
10/803,259	03/18/2004	☐

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY ☒ RATE ($)	SMALL ENTITY ☒ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 06/20/2008

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 12	Minus	** 20	= 0	X $25 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $105 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/PATRICIA LEWIS/

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,259	03/18/2004	Ralph B. Lilly	Anon-001:C	5397

21897 7590 02/22/2008

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EXAMINER	
NAJARIAN, LENA	

ART UNIT	PAPER NUMBER
3626	

MAIL DATE	DELIVERY MODE
02/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/803,259	LILLY ET AL.	
	Examiner	Art Unit	
	LENA NAJARIAN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-10 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 12/26/07. Claims 23 and 24 are newly added. Claims 1-4, 6-10, and 22-24 are pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 22 is rejected under 35 U.S.C. 102(e) as being anticipated by Cunningham (US 6,859,780 B1).

(A) Claim 22 has not been amended and is rejected for the same reasons given in the previous Office Action, and incorporated herein.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-4 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1) in view of Borsand et al. (US 2003/0074225 A1).

(A) Claims 1-4 and 6 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

6. Claims 7-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1) in view of Borsand et al. (US 2003/0074225 A1), and further in view of Munoz et al. (US 2002/0052760 A1).

(A) Claims 7-10 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

7. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1) in view of Edelson et al. (5,737,539).

(A) Referring to claim 23, Cunningham does not disclose wherein the one or more patterns from the prescriptive history would indicate prescription duplication, or multi-source prescription abuse.

Edelson discloses wherein the one or more patterns from the prescriptive history would indicate prescription duplication, or multi-source prescription abuse (col. 27, lines 32-54 of Edelson).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Edelson within Cunningham.

The motivation for doing so would have been to control abuse by refusing to process the prescription (col. 27, lines 32-54 of Edelson).

8. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham (US 6,859,780 B1) in view of Borsand et al. (US 2003/0074225 A1), and further in view of Edelson et al. (5,737,539).

(A) Referring to claim 24, Cunningham and Borsand do not disclose Cunningham does not disclose wherein the one or more patterns from the prescriptive history would indicate prescription duplication, or multi-source prescription abuse.

Edelson discloses wherein the one or more patterns from the prescriptive history would indicate prescription duplication, or multi-source prescription abuse (col. 27, lines 32-54 of Edelson).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Edelson within Cunningham and Borsand. The motivation for doing so would have been to control abuse by refusing to process the prescription (col. 27, lines 32-54 of Edelson).

Response to Arguments

9. Applicant's arguments filed 12/26/07 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 12/26/07.

(A) Applicant argues that Cunningham does not teach, disclose or even suggest obtaining a *prescriptive history* of a *selected prescriptive medication purchaser*.

(B) Applicant argues that Cunningham never discloses, or even suggests, generating a *pattern* from the prescriptive history. Cunningham does not teach, disclose, or even suggest any means for indicating or determining a possibility of prescription abuse.

(C) Applicant argues that there is no teaching or suggestion to compare a *prescriptive history* with a *new prescriptive medication*.

(1) As per the first argument, the Examiner respectfully submits that Cunningham discloses that "prescriber and pharmacy transactions are all monitored and recorded by the central computing station" (see col. 6, lines 53-55 of Cunningham). Furthermore, Cunningham discloses a database for storing data and information communicated to the central computing station (see col. 4, lines 40-44 of Cunningham). The Cunningham system "manages, tracks, and records selected transactions involving the participating prescribers, pharmacies and patients" (see col. 3, lines 4-10 of Cunningham). As such, the broadest reasonable interpretation of "a prescriptive history" would include the recording of prescription transactions disclosed in Cunningham. Moreover, the claim does not specify the extent of the prescriptive history. The claim merely recites *a* prescriptive history.

(2) As per the second argument, the Examiner respectfully submits that Cunningham discloses that "in order to help combat prescription *fraud*, new systems must be developed that allow prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs...." (see col. 2, lines 55-59 of Cunningham). In addition, Cunningham's tracking of refills is clearly a way of determining a possibility of prescription abuse. Cunningham teaches that a "patient is precluded from securing additional refills without a new prescription" (see col. 3, lines 53-67 of Cunningham).

(3) As per the third argument, the Examiner respectfully submits that before a prescription is filled in Cunningham, there is a comparison conducted to detect if there are any refills left (see col. 3, lines 54-67 of Cunningham). As such, the Examiner interprets the decremented refills as a form of prescriptive history.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied prior art teaches a medical service and prescription management system (US 2003/0050802 A1); and a prescription verification system (US 6,687,676 B1).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LENA NAJARIAN whose telephone number is (571)272-7072. The examiner can normally be reached on Monday - Friday, 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. N./
Examiner, Art Unit 3626
In
2-14-08

/C. Luke Gilligan/
Primary Examiner, Art Unit 3626

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10) Applicant(s): Lilly, et al.			Docket No: Anon-001:C	
Application No. 10/803,259	Filing Date 03/18/2004	Examiner Najarian, Lena	Customer No. 021897	Group Art Unit 3626

Invention: Controlled Substance Tracking System and Method

I hereby certify that the following correspondence:

Transmittal Letter (General - Patent Pending), and all documents referenced therein

(Identify type of correspondence)

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

June 20, 2008
(Date)

Jennifer Castaneda
(Typed or Printed Name of Person Mailing Correspondence)

Jennifer Castaneda
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TRANSMITTAL LETTER
(General - Patent Pending)

Docket No.
Anon-001:C

In re Application Of: **Lilly, et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/803,259	03/18/2004	Najarian, Lena	021897	3626	5397

Title:
Controlled Substance Tracking System and Method

COMMISSIONER FOR PATENTS:

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Signature

Dated: **June 20, 2008**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Ralph B. Lilly	§	
	§	Attorney Docket: Anon-001:C
Serial No.: 10/803,259	§	Examiner: Lena Najarian
Filed: March 18, 2004	§	Art Unit: 3626
For: Controlled Substance Tracking System and Method	§	Confirmation No.: 5397

COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AFTER FINAL REJECTION

Sir:

Responsive to the Office Action dated February 22, 2008, as extended by a one-month extension of time, please amend the above-identified application as follows:

IN THE CLAIMS

Please amend the claims as indicated in the following CURRENT STATUS OF CLAIMS.

CURRENT STATUS OF CLAIMS

1. (Original) A method for tracking prescriptive medication, to address and control prescription drug abuse, said method comprising:

providing respective computer connections to a plurality of entities, said plurality of entities comprising a plurality of both affiliated and unaffiliated pharmacies;

storing pharmaceutical computer data related to prescriptive medication purchases obtained by a plurality of prescriptive medication purchasers from said plurality of affiliated and unaffiliated pharmacies; and

selectively transferring said pharmaceutical computer data through said computer connections to at least one of said plurality of entities for obtaining a prescriptive history of a selected prescriptive medication purchaser for all prescriptive medications purchased in the aggregate by said selected prescriptive medication purchaser from all of said plurality of affiliated and unaffiliated pharmacies based on said transferred pharmaceutical computer data; and

generating from said prescriptive history of said selected purchaser one or more patterns which can be used by one or more viewers of said prescriptive history to flag the possibility of prescriptive drug abuse.

2. (Original) A method of Claim 1, further comprising:

providing that said at least one of said plurality of entities comprises a physician's office and said selected prescriptive medication purchaser is a patient of said physician; and

said physician's office utilizing said pharmaceutical computer data to verify said prescriptive history of said selected prescriptive medication purchaser.

3. (Original) The method of Claim 1, further comprising:

providing that said at least one of said plurality of entities comprises a pharmacy with a pharmacist;

said selected prescriptive medication purchaser requesting that said pharmacist fill a new prescriptive medication; and

said pharmacist utilizing said pharmaceutical computer data to compare said new prescriptive medication with respect to said prescriptive history of said selected prescriptive medication purchaser.

4. (Original) The method of Claim 3, further comprising:

said pharmacist accepting or declining to fill said new prescriptive medication based on said prescriptive history.

5. (Cancelled)

6. (Original) The method of claim 1, further comprising:

providing that at least one of said plurality of entities comprises a hospital and said selected prescriptive medication purchaser is a patient of said hospital; and

said hospital utilizing said pharmaceutical computer data to determine said prescriptive history of said selected prescriptive medication purchaser.

7. (Original) The method of claim 1, further comprising:

providing that said pharmaceutical computer data for each of said prescriptive medication purchases comprises a name of a respective prescriptive medication purchaser, an address of said respective prescriptive medication purchaser, a drug prescribed, said respective prescriptive medication purchaser, a quantity of said drug, a dosage of said drug, a pharmacist name, and a doctor name.

8. (Original) The method of claim 7, further comprising:

searching said stored pharmaceutical computer data based on one or more of said name of a respective prescriptive medication purchaser, said address of said respective prescriptive medication purchaser, said drug prescribed, said respective prescriptive medication purchaser, said quantity of said drug, said dosage of said drug, said pharmacist name, and said doctor name.

9. (Original) The method of claim 7, further comprising:

storing pharmaceutical data related to whether a request for filling a prescriptive medication is filled or declined.

10. (Original) The method of claim 9, further comprising:

providing that at least one of said plurality of entities comprises a government agency.

11-21. (Cancelled)

22. (Currently Amended) A method for tracking prescriptive medications, to address and control prescription drug abuse, said method comprising;

providing respective computer connections to a plurality of entities, said plurality of entities [[comprising at least one of a group comprising]] being a group consisting essentially of a plurality of hospitals, a plurality of doctors, and at least one government agency, [[and a plurality of doctors;]], or combinations thereof;

storing pharmaceutical computer data relating to prescriptive medication purchases obtained by a plurality of prescriptive medication purchasers from a plurality of pharmacies;

selectively transferring said pharmaceutical computer data through said computer connections to at least one of said plurality of entities for obtaining a prescriptive history of a selected prescriptive medication purchaser for all

prescriptive medications purchased in the aggregate by said selected prescriptive medication purchaser from all of said plurality of pharmacies based on said transferred pharmaceutical computer data; and

generating from said prescription history of said selected purchaser one or more patterns which can be used by one or more viewers of said prescriptive history to flag the possibility of prescriptive drug abuse.

23. (Previously Presented) The method of claim 22, wherein the one or more patterns generated from the prescription history would indicate prescription duplication, or multi-source prescription abuse.

24. (Previously Presented) The method of claim 1, wherein the one or more patterns generated from the prescription history would indicate prescription duplication, or multi-source prescription abuse.

REMARKS

Reconsideration is respectfully requested for the Examiner's characterization of this current Office Action as being a Final Office Action. It is respectfully submitted that the characterization of this Office Action as being a Final Action is premature and is not supported by the facts.

The Examiner, on the one hand, has acknowledged that claims 1-4, 6-10 and 22-23 were not amended in the response to the Office Action dated September 26, 2007. On the other hand, the Examiner concludes in paragraph eleven (11) of this current Office Action that the Applicant's Amendment necessitated the new grounds of rejection presented in this Office Action.

Moreover, Claim 1 and Claim 22, the only independent claims in this application, each calls for the generation based upon the prescriptive history of a selected purchaser, one or more patterns which can be used to flag the possibility of drug abuse. In paragraph seven (7) and eight (8) of the current Office Action, the Examiner acknowledges, "Cunningham does not disclose that the one or more patterns from the prescriptive history would indicate prescription duplication, or a multi-source prescription abuse."

In light of the fact that the Examiner acknowledges that the Cunningham '780 reference and the Borsand et al '225 reference do not teach or suggest the generation of one or more patterns which are indicative of prescription drug abuse, there does not seem to be any support for the concept that the previous amendment filed by the Applicant necessitated the characterization of this previous amendment as necessitating the new grounds of rejection presented in

this Office Action. It is therefore respectfully submitted that the finality of this Office Action should be withdrawn.

Consideration is respectfully requested for Claims 1-4, 6-10 and 23-24, said claims having been variously rejected as follows:

Claims 1-4 and 6 have been rejected under 35 USC 103 as being unpatentable over the Cunningham '780 patent in view of the Borsand et al '225 reference, on the same basis as given in the previous Office Action. This rejection is respectfully traversed.

In paragraph nine (9) of this present Office Action, which covers page five and page six, the Examiner refers to column two, lines 55-59 of Cunningham, the statement that "Cunningham discloses that in order to help combat prescription fraud, new systems must be developed that allow prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs. This statement of Cunningham has absolutely nothing to do with the present invention. If one looks carefully at the Cunningham reference, it is directed pure and simple to a system, which keeps a person from obtaining more than the authorized number of refills. It is does not generate any patterns – it is simply keeps someone from obtaining additional refills once the authorized number has been reached. This is a system like that used in every pharmacy in this country. For example, the doctor may provide a patient with a prescription showing six refills. Once the six refills have been accomplished, the patient has to go back to the doctor. That is not what this invention is about. The Examiner's statement that "in addition, Cunningham's tracking of refills is clearly

a way of determining a possibility of prescription abuse," is anything but a way of determining such abuse.

This present invention is directed to something much greater than merely monitoring the prescription history of the patient. This present invention, and its two independent Claims 1 and 22, each calls for the generation of patterns which can be observed to provide indicia of drug abuse. This is an important advance in the history and the future of preventing drug abuse in this country. The Examiner has repeated her rejection of Claims 1-4 and 6 for the same reasons as set forth in the previous Office Action but these rejections are based upon error. There is no teaching in either Cunningham or Borsand et al, calling for generation of patterns indicative of drug abuse.

Claims 7-10 have also been rejected under 35 USC 103 as being unpatentable over Cunningham in view of Borsand et al, and further in view of the Munoz '760 reference. The same reasons as set forth above with respect to Claim 1, upon which Claims 7-10 are dependant, likewise distinguish Claims 7-10 over the sighted references. The Munoz '760 patent clearly shows that just like Cunningham and Borsand et al, the Munoz patent has no teaching, disclosure or even suggestion of generating patterns from the prescription history of drug abuse. The Munoz reference merely provides an electronic system to properly identify the drug being dispensed and to properly identify the patient. (See paragraph 0014 on page 2) A careful reading of the Munoz reference fails to provide any teaching or suggestion of generating patterns within the

computerized system which could possibly identify fraud or misuse of prescribed medicines.

Finally, the Examiner has rejected Claim 23 under 35 USC 103 as being unpatentable over Cunningham and the newly cited reference Edelson et al 5,737,539. With respect to paragraph seven (7) of the present Office Action, it is again reiterated that Cunningham does not disclose one or more patterns from the medical history which would indicate prescription abuse. The Examiner alleges that Edelson discloses that one or more "patterns" from the prescriptive history would indicate prescription duplication or prescription abuse.

It is quite clear that the Edelson '539 patent has no such disclosure or even a suggestion. The Examiner's attention is respectfully directed to the Title of the '539 patent and also to the first line of the Abstract. This same language is also found in every one of the claims of the Edelson '539 patent. There is no question that what is contemplated by the '539 patent was a good invention in replacing manual prescriptions which are typically handwritten and easily misread by any pharmacy in attempting to read the physician's handwriting. However, there is no teaching or suggestion of using a central computerized system capable of generating from a given patients prescriptive history one or more patterns to flag the possibility of prescriptive drug abuse. Edelson '539 patent does not describe patterns of any sort. As a consequence, the combination of Edelson '539 with three other references which likewise do not generate such patterns, such as Cunningham '780, Borsand et al '225 and

Munoz '760, do not result in the called for language of generating patterns indicative of prescription abuse, as called for in the independent Claims 1 and 22.

Perhaps more importantly, however, Claims 1 and 22 each calls for method steps which selectively transfer pharmaceutical computer data through computer connections to a group of entities (the plurality of entities being affiliated and unaffiliated pharmacies in the case of Claim 1) and a group of entities consisting essentially of a plurality of hospitals, a plurality of doctors, and at least one government agency (in the case of Claim 22).

There are absolutely no teachings or suggestion of this selective transferring of this data to such plurality of entities, in either the Edelson reference, or the Cunningham reference, or the Borsand et al reference, or the Munoz reference.

The Applicants therefore respectfully submit that Claims 1-4, 6-10 and 22-24, as currently amended are patentable over the cited art of record and it is respectfully requested that these claims be allowed and that the application be advanced to issue.

Respectfully Submitted,

Date 6/20/08

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Notice of References Cited

Application/Control No.	Applicant(s)/Patent Under Reexamination	
10/803,259	LILLY ET AL.	
Examiner	Art Unit	Page 1 of 1
LENA NAJARIAN	3626	

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,737,539	04-1998	Edelson et al.	705/3
*	B	US-6,687,676 B1	02-2004	Denny, Lawrence A.	705/2
*	C	US-2003/0050802 A1	03-2003	Jay et al.	705/3
	D	US-			
	E	US-			
	F	US-			
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	I	US-			
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FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.